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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,507	05/06/2002	Dirk Wernicke	3658-0103P	5925

2292 7590 07/07/2003

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/979,507

Applicant(s)
Wernicke et al.

Examiner
Ralph Gitomer

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 30, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Apr 30, 2003 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

The formal drawings and amendment to the specification received 4/30/2003 have been entered and claims 13-23 are currently pending in this application. The amended specification is acceptable; the amended title is not acceptable because it does not meet the requirements of a proper title and is too long.

This Office Action is made non-final because the English translation is now available and provided herein of the Fujimoto reference previously cited. And an update search revealed a new reference by Falduto.

In view of the all new claims submitted, all previous rejections of record are hereby withdrawn.

A reading of the specification and claims reveals the point of novelty resides in the connection between collagenase 3 as a prognostic marker for rheumatoid arthritis. How the collagenase 3 is determined does not appear to be novel. No unexpected results are seen in the selection of the specific single collagenase 3 MMP as compared to any other known MMP and no results are claimed.

Claims 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Table 1 on page 8 of the specification is presented to show a relation between collagenase 3 and present severity of RA, possibly as a disease activity marker or index component. It is interpreted that in the first column of numbers, 60% of the subjects had some unknown degree of collagenase 3 expression as defined by Rheumatoid factor positive. In the second column, 66% were Rheumatoid factor positive. It appears the two separate columns are from different cohorts. But the purpose of the studies would be to determine if there is some difference between those who do and those who do not show some unknown amount of collagenase 3 in the synovial membrane. No such data is presented.

Further, the new claims are directed to determining the prognosis of progression of RA, the evaluation of clinical course, and detecting an increased genetic predisposition to RA. The specification as originally filed provides no description of how the claimed method steps accomplish these functions nor how one would use the data obtained from the method steps to accomplish any useful interpretation of the claimed methods. It is well known in this art that RA typically has a highly variable and unpredictable course and no evidence or data is presented to enable one to predict anything about the prognosis of the disease.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

5 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by
10 the applicant for patent.

15 The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).
20

Claims 13-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Falduto.

25 Falduto (6,399,371) with a 102(e) date of 3/1997, entitled ~~Human~~ Human Matrix Metalloprotease Gene, Proteins Encoded Therefrom and Methods of Using Same~~te~~ teaches determining collagenase 3 and rheumatoid arthritis. In column 2 lines 38 to end, unregulated activity of MMP's is responsible for the joint degradation observed in rheumatoid arthritis. Activated forms of MMP's and
30 their products are found in synovial fluids and joint tissues in abnormally high amounts. These arthritic tissues also show a greater than normal expression of MMP's. Activities of MMP's in normal tissues are thought to be regulated by the presence of endogenous tissue inhibitors of MMP's and the balance may result

in RA. In column 3, line 36 to end, it would be advantageous to provide specific methods and reagents for the prognosis, monitoring, prevention or treatment of diseases and conditions associated with imbalances in the production or activity of MMP's or to indicate possible predisposition to these conditions. mRNA and antibody related determination methods are discussed. Therapy can be monitored using the methods. In column 5 lines 7-8, collagenase 3 as an MMP is shown. In column 11 lines 12-23, the sample may be a body component such as antibodies or antigens including fluids, cells, and tissue specimens. In column 25 last paragraph, methods of screening for drugs to treat arthritis are shown.

It is noted the present claims are drawn specifically to collagenase 3 only, however Falduto sets forth a number of MMP's including collagenase 3 for the same function as presently claimed.

Claims 13-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 13 lines 5-6 and all occurrences, ~~is~~ is able to ~~do~~ does not state what may actually occur and may be intended to be written ~~that~~ that binds to collagenase 3 mRNA~~.~~. In claim 13 line 7,

bounded substance is not understood in context and may be intended to be deleted. In the preamble of claim 14, what the predisposition is increased by is not seen. In claim 18 line 2, its is unclear as to what may be referred to and may be intended to be deleted. In claim 19 inter alia operative interventions lacks antecedent basis and is indefinite as to what may be intended. Claim 21 is not understood regarding what markers are encompassed nor how they are used.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Lund (US 2002/0099004 A1) teaches determining collagenase 3 and rheumatoid arthritis.

De Saint-Vis (6,271,014) teaches determining collagenase 3.

Fujimoto (JP 08-226918) English translation provided, teaches determining MMP's in a tissue or humor to enable diagnosis or monitor pathology of disease including arthrosis in the abstract. Antibodies and tissue inhibitor or both may be used. On page 1 collagenase 3 (MMP-13) is described. On page 12 last paragraph, determining MMP's is important in rheumatoid arthritis diagnosis.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

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